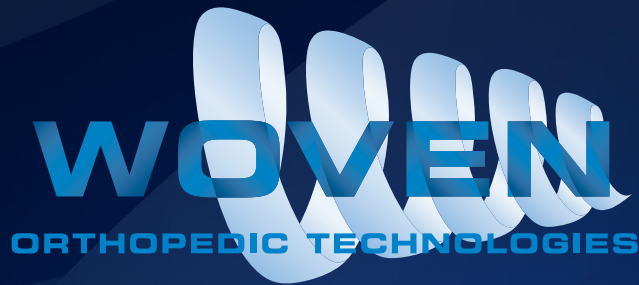


OGMEND[®] IMPLANT SYSTEM

SURGICAL TECHNIQUE GUIDE
SPINE

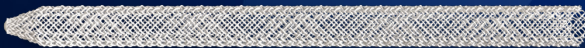
WOVEN
ORTHOPEDIC TECHNOLOGIES



OGmend[®]

Spine Surgical Technique Guide

This document describes the proper surgical technique to use the OGmend[®] Implant System.



OGMEND[®]

IMPLANT SYSTEM

SURGICAL TECHNIQUE GUIDE

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Caution: USA Federal Law restricts this device to sale by or on the order of a physician.

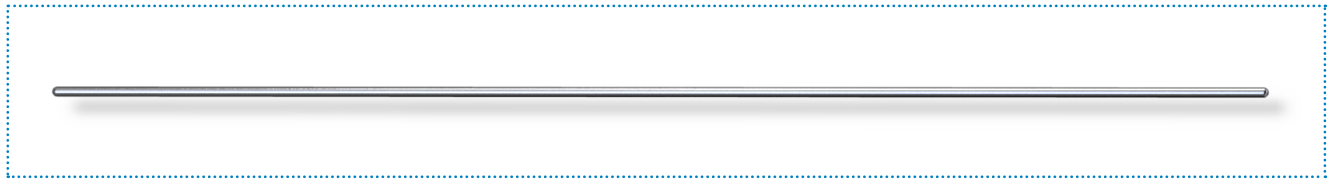
1 System Description

The OGMend® Implant System, comprised of the OGMend® Implant and the OGMend® Inserter, provides an interface for screw engagement with the surrounding bone by increasing mechanical wedging.

OGMend® Implant



OGMend® Inserter



2 Indications

The OGMend® Implant System is indicated for use with spinal fixation devices where the screw has lost purchase due to screw loosening, back out or breakage.

3 Precautions

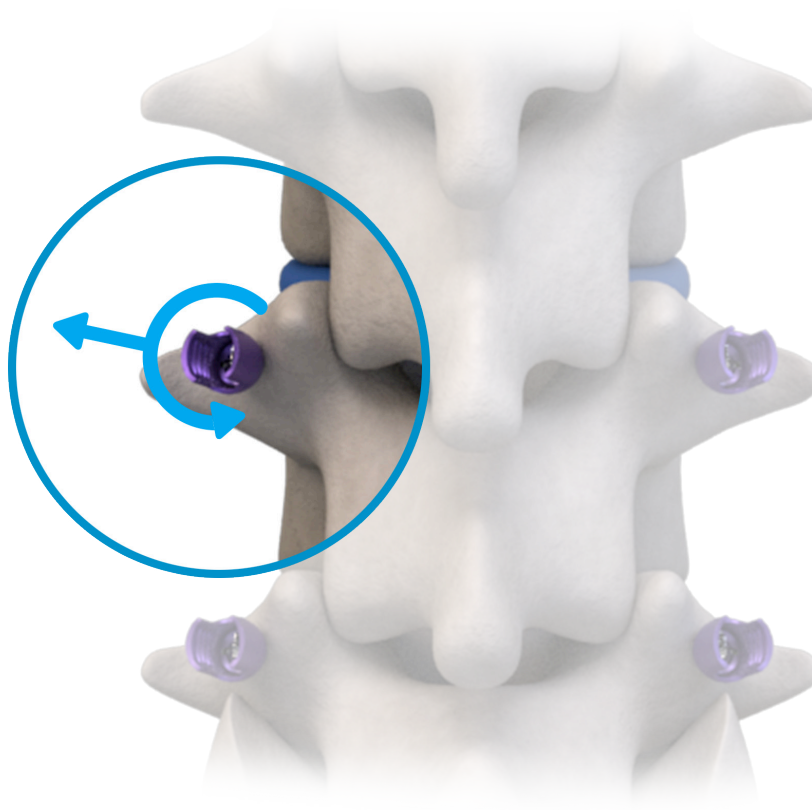
Physicians implanting the device must refer to the Instructions for Use (WVN0161) for a complete listing of contraindications, warnings, and precautions associated with the use of the OGMend® Implant.

4 Surgical Approach

1. Removal of Loose Screws (If Applicable)

Using the appropriate driver, remove any previously implanted screws by rotating the driver counter-clockwise until the screw becomes free.

Note: If the screw cannot be removed with the driver, see the screw manufacturer's guide for recommended removal technique.



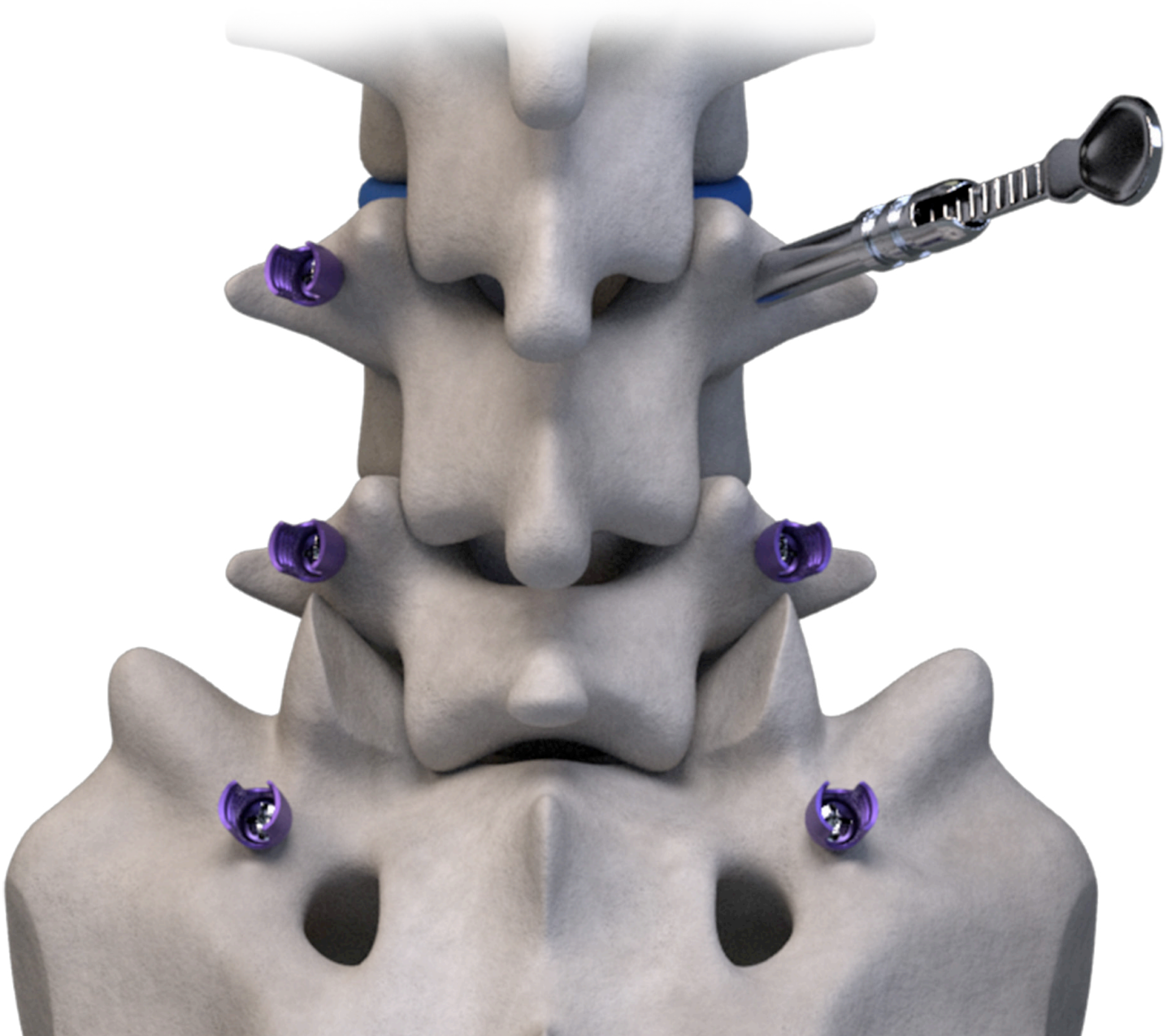
For clinical conditions where the bone is determined to be compromised prior to screw insertion:

- Create a pilot hole using a pedicle probe.
- Insert the pedicle tap into the hole and create a screw trajectory to the vertebral body.
- Follow the instructions for OGMend® insertion as described.

Note: The diameter of the pedicle tap should always mirror the diameter of the pedicle screw.

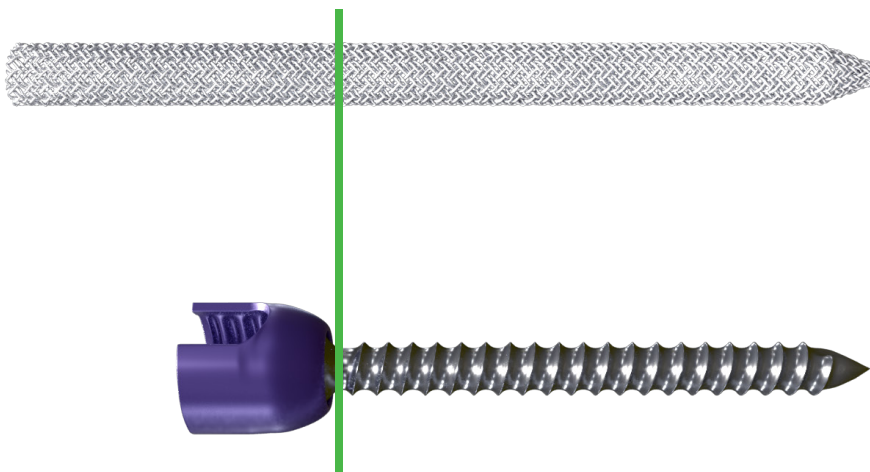
2. Identify the Correct Length for OGMend® Implant

Use a depth gauge or pedicle tap to measure the length of the hole in which the OGMend® Implant will be inserted. Based upon the length measured, determine the appropriate screw length that will be used. This length will guide the length to which the OGMend® Implant will be cut in the following step.

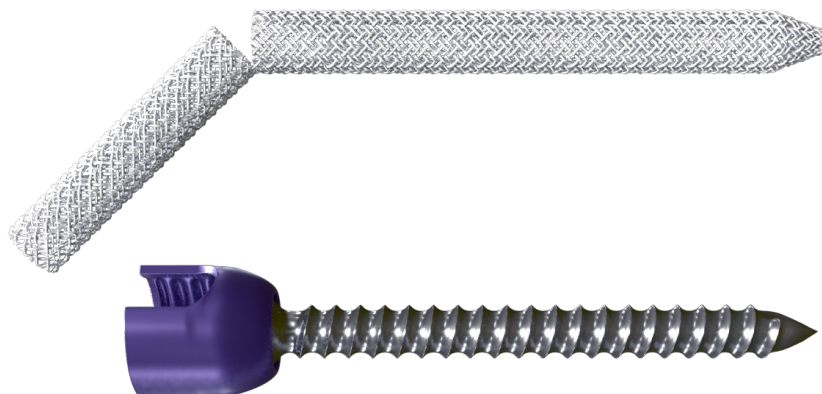


3. Cut the OGMend® Implant to the Length Required

a. Measure the length of the screw being used from the distal tip (blue bar) to the base of the screw head (green bar). Measure the same length on the OGMend® Implant, starting from the closed, distal end of the OGMend® Implant and progressing towards the opposite end. Once you reach the designated length, add 3 mm to identify the spot at which to cut the OGMend® Implant to size in the following step.

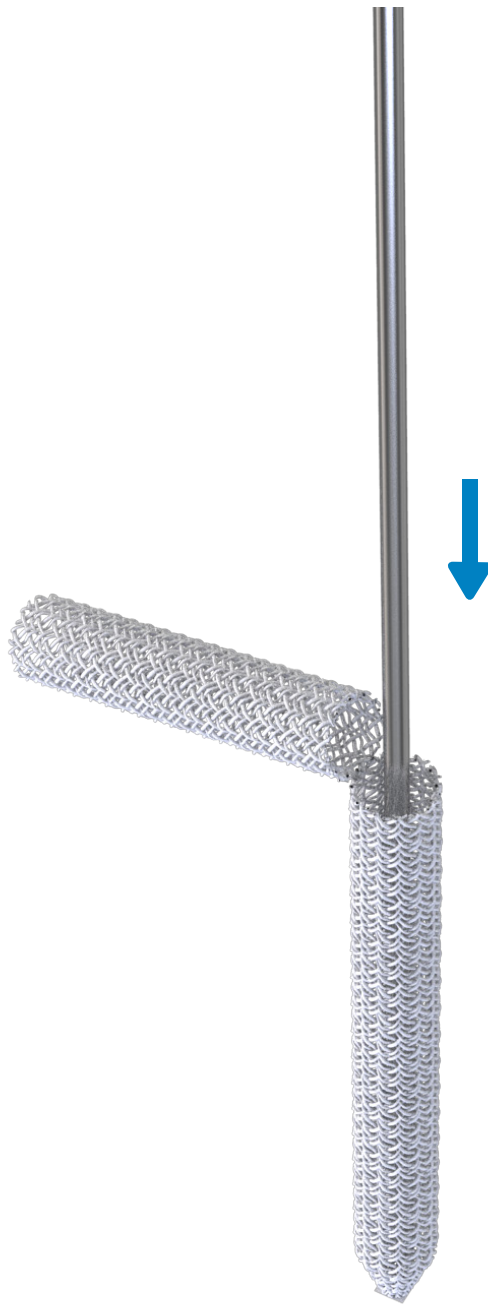


b. Using a pair of scissors, partially cut the OGMend® Implant at the point measured in the step above. Leave 3-5 fibers attached between the cut end and the remainder of the OGMend® Implant to create a “tab” to hold for proper placement and positioning during insertion.



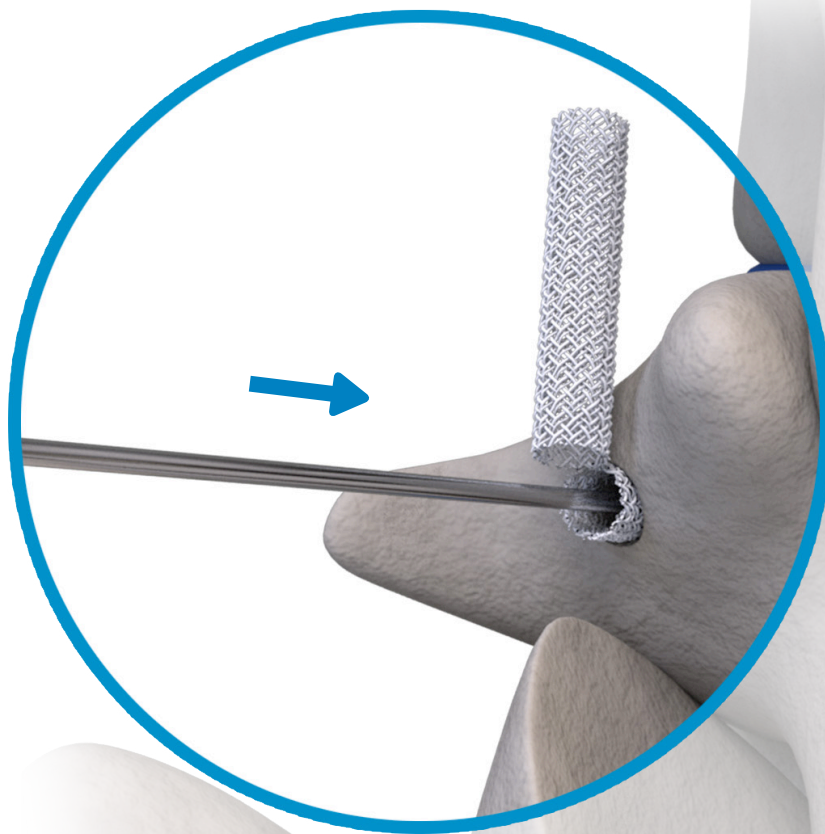
4. Assemble on Inserter

Pass the Inserter through the center of the OGMend® Implant, bypassing the tab created in the previous step.



5. Insert the OGMend® Implant into the Pedicle

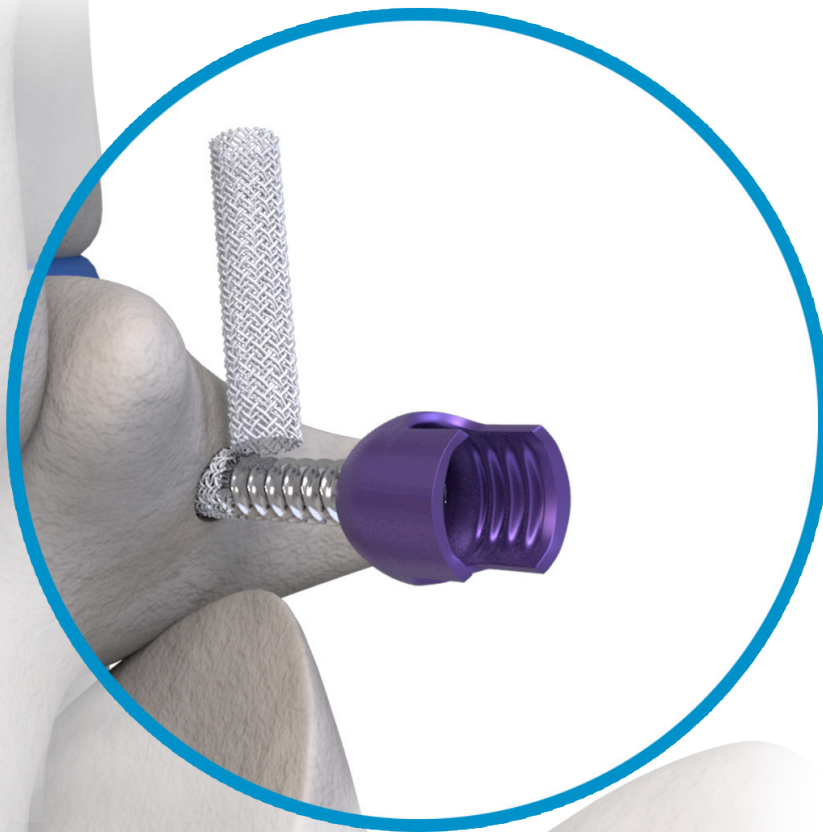
Use the Inserter to place the OGMend® Implant into the hole created by the previous screw or pedicle tap. Place the OGMend® Implant into the hole so that the portion showing is level or slightly above the level of the hole. Use the tab to re-position the OGMend® Implant if needed by pulling the tab proximally.



6. Partially Place the Screw into the OGMend® Implant

While holding the tab, place the new screw into the OGMend® Implant. Continue holding the tab and drive the screw into the hole until approximately 50% of the screw is embedded within the OGMend® Implant.

Note: While inserting the screw, use the tab to reposition the OGMend® Implant if needed.



7. Remove the “Tab” from the OGMend® Implant

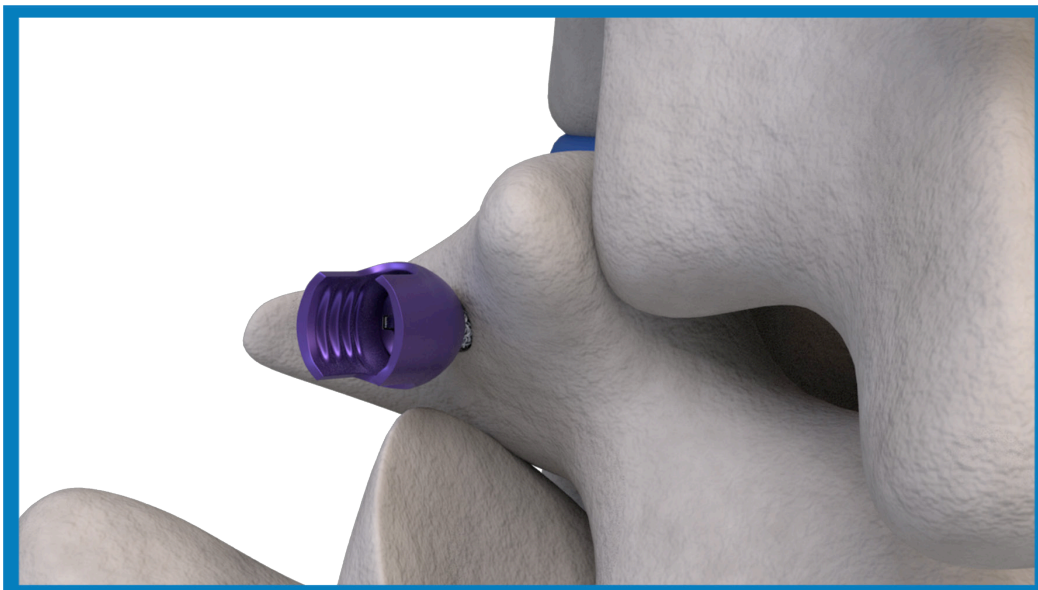
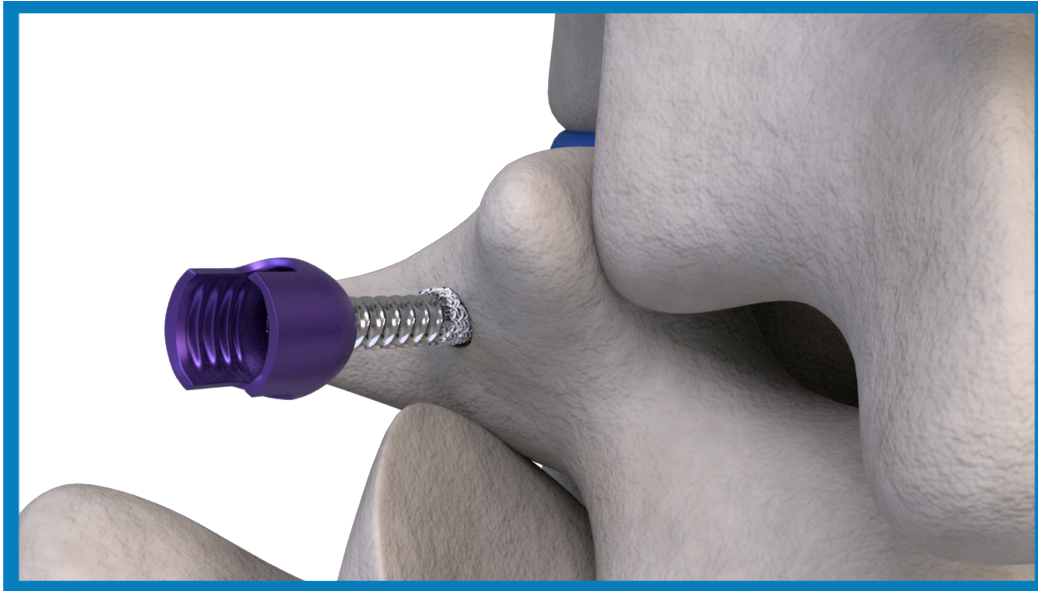
Use a scalpel or scissors to cut the remaining fibers and remove the tab. Discard the tab after removal.

Note: Use caution while cutting the remaining fibers to ensure that the screw threads are not damaged.



8. Complete the Placement of the Screw

Drive the screw into its final position. Ensure that the OGMend® Implant does not impede or obstruct the screw tulip.



Repeat steps 1–8 for additional screws.

5 Removal Instruction (If Required)




Implantation Removal Instructions

1. Use the preferred screw removal tool and technique per manufacturer’s instructions.
2. Remove the OGMend® Implant.

6 System Components

System Description

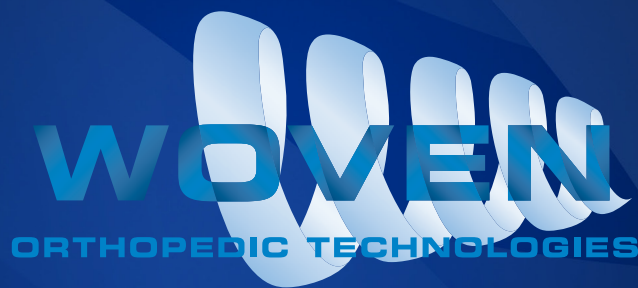
OGMend® Implant is available in three (3) sizes: small, medium, and large as detailed below.

	Small		Medium*		Large	
Screw Diameter Range (mm)	1.5	3.5	3.5	6.5	6.5	10.5
Diameter "At-Rest"	ø3.5mm		ø6.5mm		ø8.5mm	
						

*Currently available in medium size only.

Suggested Additional Tools (not included in the OGMend® Implant):

- Scalpel with No. 2 Blade
- Scissors
- Depth Gauge



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